



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,888	06/14/2001	Joseph P. Steiner	23138A-T	7207

29728 7590 12/31/2002  
GUILFORD PHARMACEUTICALS C/O  
FOLEY & LARDNER  
3000 K STREET, NW  
WASHINGTON, DC 20007-5143

EXAMINER

COOK, REBECCA

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
[www.uspto.gov](http://www.uspto.gov)

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 14

Application Number: 09/879,888  
Filing Date: June 14, 2001  
Appellant(s): STEINER ET AL.

---

Sean Passino  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed October 8, 2002.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

Art Unit: 1614

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

No amendment after final has been filed.

**(5) *Summary of Invention***

The summary of invention contained in the brief is deficient because while claims 17-32 are directed to a pharmaceutical composition for treating alopecia or promoting hair growth, claim 33 recites a "pharmaceutical composition."

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

The rejection of claims 17-32 provisional rejected under the judicially created doctrine of obviousness-type double patenting stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

The rejection of claim 33 under 102(b) is argued separately.

**(8) *Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

✓ 5,801,187	Li et al.	September 1998
✓ 6,200,972	Li et al.	April 2001
✓ 6,218,544	Li et al.	March 2001

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

**Rejection under 102(b)**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by 5,801,187 (column 6, Formula I, column 9, line 50 through column 11, line 15), 6,200,972 (column 3, Formula I, column 10, line 62 through column 12, line 24, claim 5) and 6,218,544 (column 3, Formula I, column 10 line 9 through column 11, line 40).

Each reference discloses a compound having the limitations of the compound recited in claim 33 and that it is used in a pharmaceutical composition comprising said compound and a pharmaceutically acceptable carrier. Both the compound of the instant claim and the compound of Formula I of the prior art are a nitrogen-containing

Art Unit: 1614

heterocyclic compound having two or more heteroatoms; each compound has a substituent -C(W)-C(Y)- which is attached to a nitrogen atom of the heterocyclic ring, wherein W and Y are independently selected from the group consisting of O, S, CH<sub>2</sub> and H<sub>2</sub>; wherein each compound is additionally substituted with an ester or amide substituent, when X is O and Z is O, NH or NR<sub>1</sub> in the compound of Formula I.

Furthermore, the compound of formula I of the prior art is not an N-oxide of an ester or amide and the amide substituent is linked to the heterocyclic ring with a carbon-carbon bond. Each reference further discloses that said the invention of the reference is to a pharmaceutical composition comprising an effective amount of the compound of Formula I and a pharmaceutically acceptable carrier.

**Rejection under the judicially created doctrine of obviousness-type double patenting.**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

Art Unit: 1614

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 6, 8 of copending Application No. 09/784,174. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims read on the claims of '174 when J and K in '174 form a heterocyclic ring.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claims 17-31 are to a pharmaceutical composition comprising a nitrogen-containing heterocyclic compound having two or more heteroatoms. Claim 32 is to a heterocyclic compound having two or more heteroatoms when V is N. All of the claims further recite a second hair revitalizing agent and a pharmaceutically acceptable carrier.

Claims 5, 6, and 8 of '174 are to a pharmaceutical compositions comprising a compound of Formula I, II and IV respectively in which J and K may be taken together to form a heterocyclic ring which is substituted with a second heterocyclic atom. The claims further recite a second hair revitalizing agent and a pharmaceutically acceptable carrier.

Art Unit: 1614

The instant claims read on the claims of '174 when J and K in '174 form a heterocyclic ring and the heterocyclic ring in both '174 and '888 are each substituted with the same second heterocyclic atom.

In the absence of a terminal disclaimer to the instant application there would be an extension of monopoly on the first issuing application.

**(11) Response to Argument**

Appellants argue that the rejection under 35 U.S.C. 102(b) to claim 33 is improper because the compound of Formula I recites a compound and not a composition. However, the references anticipate the composition of instant claim 33 for the reasons given above.

Appellants' argue that overlap cannot establish a case of nonstatutory obviousness-type double patenting. This is not persuasive for the reasons given above. The compositions of both '174 and '888 include heterocyclic compounds that are the same when the compounds of '174 have heterocyclic rings and the heterocyclic rings of both '174 and '888 are each substituted with the same second heterocyclic atom. Furthermore, in the absence of a terminal disclaimer to the instant application there would be an extension of monopoly on the first issuing application.

For the above reasons, it is believed that the rejections should be sustained.

Application/Control Number: 09/879,888  
Art Unit: 1614

Page 7

Respectfully submitted,



Rebecca Cook  
Primary Examiner  
Art Unit 1614

RC  
December 28, 2002

Conferees

GUILFORD PHARMACEUTICALS C/O  
FOLEY & LARDNER  
3000 K STREET, NW  
WASHINGTON, DC 20007-5143

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNICAL CENTER 1600



RAYMOND HENLEY, III  
PRIMARY EXAMINER  
GROUP 1600